

alleging that the article had been shipped in interstate commerce on or about December 21, 1939, by Brookgate Remedies Co. from Evansville, Ind.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of phenolic compounds, including 5.44 percent of carbolic acid, camphor, and turpentine in an ointment base.

The article was alleged to be misbranded in that the following statements on the label were false and misleading, since it would not be efficacious for the purposes for which it was so recommended: "For all cases of Inflammation or Infection. For * * * Mashed Members, Cinders or any other Foreign substances in the Eye." It was alleged to be misbranded further in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Apply salve freely to affected parts and bandage. For cinders or other foreign substance in eye, place salve on absorbent cotton and place same over closed eye and bandage."

The product was also alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in notice of judgment No. 103 published under that act.

On January 26, 1942, the shipper having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS FOR USE OR WARNING STATEMENTS¹

439. Misbranding of Pine-Orum Compound. U. S. v. John C. Schaffer (Pine-Orum Chemical Co.). Plea of guilty. Fine, \$50. (F. D. C. No. 4169. Sample No. 11224-E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of certain conditions and failed to comply with certain mandatory labeling requirements of the law as indicated hereinafter.

On September 13, 1941, the United States attorney for the Southern District of Mississippi filed an information against John C. Schaffer, trading as Pine-Orum Chemical Co., at New Augusta, Miss., alleging shipment on February 23, 1940, from the State of Mississippi into the State of Texas of a quantity of Schaffer's Pine-Orum Compound that was misbranded.

Analysis showed that the article was a medium heavy oil having a strong pine oil odor consisting essentially of a pine tar distillate containing sulfur or sulfur compounds and a small percentage of water.

It was alleged to be misbranded in that certain statements on the bottle label were false and misleading since they represented and suggested that the article was efficacious as a treatment and remedy for coughs, colds, flu, pneumonia, headache, indigestion, worms in humans and animals, cuts, burns, infections and blood poison, insect bites, tonsillitis, sore throat, toothache, pyorrhea, bruises, rheumatism, neuritis, sprains, stiff joints, old chronic sores, hemorrhoids, athlete's foot, itch, poison oak, dew poison and dandruff; that it would be efficacious to stop the flow of blood; that when used in the bath it would have medicinal properties, and it was efficacious for many animal ailments; whereas it was not efficacious for such purposes.

It was alleged to be misbranded further in that it was in package form and did not bear a label containing the name and place of business of the manufacturer, packer or distributor, placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read under customary conditions of purchase, since the name and place of business of the manufacturer did not appear on the panel of the bottle label which was displayed under customary conditions of purchase. It was alleged to be misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents in terms of measure; in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and in that its labeling did not bear adequate directions for use, since it was recommended for conditions requiring external application and the labeling bore no directions for external use.

On October 13, 1941, the defendant having entered a plea of guilty, the court imposed a fine of \$50.

¹ See also Nos. 426, 427, 429-432, 434-436, 459, 460.